

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION**DRUG FOR HUMAN USE**

6702. Hope's Worm Rid. (F.D.C. No. 43535. S. No. 56-372 P.)

QUANTITY: 140 btls. at Charleston, S.C.

SHIPPED: 7-27-59, from Clayton, Mo., by Hope Co.

LABEL IN PART: "Hope's Worm-Rid For Pin and Roundworms * * * Each teaspoonful (5 cc.) contains: Piperazine Citrate Equivalent to 500 mg. Piperazine Hexahydrate * * * Directions: * * * Adults and children * * * The Hope Co., Clayton 5, Mo."

LIBELED: 9-19-59, E. Dist. S.C.

CHARGE: 505(a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to the law was not effective with respect to such drug.

DISPOSITION: 11-8-61. Consent—destruction.

DRUG FOR VETERINARY USE

6703. Felco Feed Premix. (F.D.C. No. 45147. S. No. 27-424 R.)

QUANTITY: 118 bales, 6 10-lb. bags each, at Fort Dodge, Iowa.

SHIPPED: 7-7-60, from Kansas City, Mo., by Farmers Elevator Service Co., Inc.

LABEL IN PART: (Bag) "Felco Feed Premix medicated for the prevention of Coccidiosis in Chickens * * * Active drug ingredients: Bithionol 10.0 percent Methitriazamine 2.0 percent * * * Manufactured for Farmers Elevator Service Company * * * Fort Dodge, Iowa."

LIBELED: 11-18-60, N. Dist. Iowa; amended libel 1-29-62.

CHARGE: 505(a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to such drug.

DISPOSITION: Claimant, Farmers Elevator Service Co., Inc., filed an answer denying the charge and alleging that said article could be legally introduced or delivered for introduction into interstate commerce, by reason of the fact that a new drug application was effective at the time of its shipment in interstate commerce; that the said article did not contain changes that were significant from the standpoint of safety of the drug and that a supplemental new drug application was not therefore required as to said article; that said article was not a new drug and thus no new drug application was necessary for said article; and that claimant had an effective application for an exemption from certification of a feed containing an antibiotic pursuant to Section 507, a necessary component of which exempted final product was said article, so that a new drug application was not required for said article in view of the provision of Section 507(e) stating that any drug subject to Section 507 shall not be subject to Section 505.

Thereafter, by permission of the court, the claimant withdrew its claim and answer without admitting the allegations of the libel, stating that no useful purpose would be served by contesting the action since a supplemental new drug application was then effective with respect to the article and that accordingly the determination of the issues involved was moot insofar as future interstate shipments of the article were concerned, and since the value of the libeled article was much less than would be the cost of defending the action. Judgment of condemnation was thereupon entered on 1-29-62, and the court ordered that the article be destroyed.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

6704. Vitamin tablets and vitamin-and-mineral tablets. (F.D.C. Nos. 46275, 46278. S. Nos. 78-747/8 R.)

QUANTITY: 94 btl., each containing 50 or 100 *vitamin-and-mineral tablets*, at Mission, Tex.; and 42 btl., each containing 50 or 100 *vitamin tablets*, at Donna, Tex.

SHIPPED: On unknown dates, from Chicago, Ill.

LABEL IN PART: (Btl.) "Olavite-M Therapeutic Vitamin & Mineral Tablets * * * Olafsen Vitamins, Inc., Dist. Chicago, Illinois. Each tablet contains * * * Folic Acid 0.5 mg. * * * Dosage: 1 or 2 tablets daily," and "Olavite Therapeutic Vitamin Tablets * * * Olafsen Vitamins, Inc., Dist., Chicago, Illinois. Each tablet contains * * * Folic Acid 0.5 mg. * * * Dosage: 1 or 2 tablets daily."

LIBELED: 8-24-61, S. Dist. Tex.

CHARGE: 503(b)(4)—while held for sale, the labels of the articles failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 10-9-61. Default—destruction.

6705. Viril-Lam tablets. (F.D.C. No. 45947. S. No. 32-285 R.)

QUANTITY: 389 25-tablet btl. at Santurce, P.R.

SHIPPED: 3-31-61, from Oceanside, N.Y., by Lambda Pharmacal Laboratories.

LABEL IN PART: "Lambda Viril-Lam Each tablet supplies: Methyl testosterone 10 mg. Pituitary extract (anterior lobe) 4 mg. Adrenals 4 mg. Yohimbine hydrochloride 5 mg. Vit. A (from Fish liver oil) 5,000 U.S.P. Units Vitamin E 1 mg. Vitamin B₁ 5 mg. Zinc Phosphide 1.5 mg. Strychnine sulfate 0.05 mg. Dosage: * * * Lambda Pharmacal Laboratories, Inc., 391 Atlantic Ave., Oceanside, N.Y."

LIBELED: 6-20-61, Dist. P.R.

CHARGE: 503(b)(4)—when shipped, the article was a drug subject to the provisions of 503(b)(1) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 8-10-61. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

6706. Candy-coated chewing gum. (F.D.C. No. 46440. S. No. 84-605 R.)

QUANTITY: 7 ctns., containing a total of 6,000 units, at New York, N.Y., in possession of Kean Energizing Health Products, Inc.

SHIPPED: 5-1-61, from Newark, N.J.

LABEL IN PART: (Plastic box) "15 One For The Road 15 Natural Coffee Base 'Drive-Safers' Pep-Ups Kean Brand Chicles Vitamin A Fortified Caffeine Activated Safe-Pleasant as Coffee * * * An Adult Product," "2 Pep-Ups* Chicles Provide the Energy & Stimulation of One Full Cup of Coffee, Chew As Many As Desired," and "Each Chicle Contains 5000 Units Vitamin A To Aid Eyesight Fatigue Resist Headlight Glare."

ACCOMPANYING LABELING: A package insert reading in part "Real Coffee Base plus Vitamin A and Caffeine"; a folder reading in part "New! Chew A Full Cup of Zesty Coffee Kean's Pep-Ups Brand"; a window streamer reading in